''acne blemishes,'' ''acne pimples,'' ''blackheads,'' or ''whiteheads'').

(iv) ''Helps prevent new'' (select one or more of the following: ''acne blemishes,'' ''acne pimples,'' ''blackheads,'' or ''whiteheads'') which may be followed by ''from forming.''

(v) ''Helps prevent the development of new'' (select one or more of the following: ''acne blemishes,'' ''acne pimples,'' ''blackheads,'' or ''whiteheads'').

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) *For products containing any ingredient identified in §333.310.* (i) ''For external use only.''

(ii) ''Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.''

(2) *For products containing sulfur identified in §§333.310 (d) and (e).* ''Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor.''

(3) *For products containing any combination identified in §333.320.* ''Apply to affected areas only. Do not use on broken skin or apply to large areas of the body.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) ''Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.''

(2) The directions described in paragraph (d)(1) of this section are intended for products that are applied and left on the skin. Other products, such as soaps or masks, may be applied and removed and should have appropriate directions.

(3) *Optional directions.* In addition to the required directions in paragraphs (d)(1) and (d)(2) of this section, the product may contain the following optional labeling: ''*Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated: (select one of the following: 'elsewhere on this label,' 'above,' or 'below.')''

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

SOURCE: 52 FR 15892, Apr. 30, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 336.1 Scope.

(a) An over-the-counter antiemetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in §330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 336.3 Definition.

As used in this part:

Antiemetic. An agent that prevents or treats nausea and vomiting.

Subpart B—Active Ingredients

§ 336.10 Antiemetic active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § 336.50(d):

(a) Cyclizine hydrochloride.

(b) Dimenhydrinate.

(c) Diphenhydramine hydrochloride.

(d) Meclizine hydrochloride.

Subpart C—Labeling

§ 336.50 Labeling of antiemetic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''antiemetic.''

(b) *Indications.* The labeling of the product states the following under the heading ''Indications,'' ''For the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness.'' Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings:''

(1) *For products containing any ingredient identified in § 336.10*—(i) *When labeled for use in adults and for those products that can be and are labeled for use in children under 12 years of age.* ''Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.''

(ii) *For those products that can be and are labeled only for children under 12 years of age.* ''Do not give this product to children who have a breathing problem such as chronic bronchitis or who have glaucoma, without first consulting the child's doctor.''

(2) *For products containing cyclizine hydrochloride identified in § 336.10(a).* ''Do not give to children under 6 years of age unless directed by a doctor.''

(3) *For products containing dimenhydrinate identified in § 336.10(b).* ''Do not give to children under 2 years of age unless directed by a doctor.''

(4) *For products containing diphenhydramine hydrochloride identified in § 336.10(c).* ''Do not give to children under 6 years of age unless directed by a doctor.''

(5) *For products containing meclizine hydrochloride identified in § 336.10(d).* ''Do not give to children under 12 years of age unless directed by a doctor.''

(6) *For products containing cyclizine hydrochloride identified in § 336.10(a) or meclizine hydrochloride identified in § 330.10(d).* ''May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.''

(7) *For products containing dimenhydrinate identified in § 336.10(b) or diphenhydramine hydrochloride identified in § 336.10(c).* ''May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing cyclizine hydrochloride identified in § 336.10(a).* Adults and children 12 years of age and over: Oral dosage is 50 milligrams every 4 to 6 hours, not to exceed 200 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed

75 milligrams in 24 hours, or as directed by a doctor.

(2) *For products containing dimenhydrinate identified in § 336.10(b).* Adults and children 12 years of age and over: Oral dosage is 50 to 100 milligrams every 4 to 6 hours, not to exceed 400 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 to 50 milligrams every 6 to 8 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 12.5 to 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor.

(3) *For products containing diphenhydramine hydrochloride identified in § 336.10(c).* Adults and children 12 years of age and over: Oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor.

(4) *For products containing meclizine hydrochloride identified in § 336.10(d).* Adults and children 12 years of age and over: Oral dosage is 25 to 50 milligrams once daily, or as directed by a doctor.

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[52 FR 15892, Apr. 30, 1987, as amended at 53 FR 35809, Sept. 15, 1988; 59 FR 16982, Apr. 11, 1994]

§ 336.80 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following additional indications.

(a) *For products containing cyclizine hydrochloride, dimenhydrinate, and diphenhydramine hydrochloride identified in § 336.10 (a), (b), and (c).* ''For the treatment of vertigo of motion sickness.''

(b) *For products containing meclizine hydrochloride identified in § 336.10(d).* ''For the treatment of vertigo.''

PART 338—NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

SOURCE: 54 FR 6826, Feb. 14, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 338.1 Scope.

(a) An over-the-counter nighttime sleep-aid drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 338.3 Definition.

As used in this part:

Nighttime sleep-aid. A drug that is useful for the relief of occasional sleeplessness by individuals who have difficulty falling asleep.

Subpart B—Active Ingredients

§ 338.10 Nighttime sleep-aid active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § 338.50(d):

(a) Diphenhydramine hydrochloride.

(b) Diphenhydramine citrate.